ignite

A CLINICAL STUDY OF VGL101 IN People with Adult-Onset Leukoencephalopathy with Axonal Spheroids and Pigmented Glia (ALSP)

This study will assess a new potential therapy for ALSP, called VGL101. The study will look at the safety of VGL101 as treatment for ALSP and will also measure the effect of the treatment on the symptoms of ALSP.

Who can participate?

Each person will need to meet the following main inclusion criteria:

- 18 years of age or older
- Documentation of a gene variant in the *CSF1R* gene
- Having clinical symptoms of ALSP
- Has a study partner (caregiver, friend, family member, etc.) who will commit to supporting throughout the study

Additional criteria for this study can be discussed with a study doctor and will be assessed during the screening period.

Where will the study take place?

The study will have sites in the following countries. Travel assistance and stipends for participation are available to participants and caregivers.

United States

Germany

Netherlands

United Kingdom

Overview of study participation

Study participation will last approximately 60 weeks (which is around 14 months).

Participants will travel to the study site to receive treatment and participate in assessments to evaluate the study treatment. Study visits will take place about every 4 weeks (around 15 visits total).

Participants will receive treatment with VGL101 approximately every 28 days during the study. The treatment will be given during clinic visits via an intravenous (IV) infusion lasting about 1 hour. Each study visit will last up to approximately 6 hours.

Vigil Neuro believes that study participation should not require a financial investment to the participant. Travel assistance and stipends for participation may be available to participants and caregivers.

Find more information

Visit the study website
alspstudy.com

View the study listing on ClinicalTrials.gov
https://clinicaltrials.gov/ct2/show/NCT05677659

Contact Vigil Neuro
alspstudy.com/contact-us

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Frequently Asked Questions about IGNITE

Do participants have to pay to be in the IGNITE study?

Vigil Neuro believes study participation should not require a financial investment to the participant. Travel assistance and stipends for participation are available to participants and caregivers.

Will all IGNITE study participants receive the treatment, or will some participants receive a placebo?

All participants will receive the investigational treatment VGL101. There is no placebo involved in the study.

Where can I learn more about whether I am eligible to participate in the IGNITE study?

More information about inclusion and exclusion criteria are listed on the **clinicaltrials.gov** website. We recommend speaking with your physician and reviewing this information with them if you are interested in exploring participation in the study. If you have additional questions, please contact us.

If I live outside of the countries where the study is being conducted, am I able to participate?

Decisions about individual enrollment, including enrollment of international participants, is left to the study investigators. You may wish to speak with your physician about your eligibility for the study based on the inclusion/exclusion criteria and you or your physician may wish to reach out to one of the study sites to express interest as it may be possible for eligible individuals who are able to travel to join a study site outside of their country of residence.

If I am in the ILLUMINATE natural history study will I automatically be involved in the IGNITE study?

No, participation in the ILLUMINATE natural history study does not guarantee enrollment into the IGNITE study. These two studies serve different research purposes and the inclusion/exclusion criteria of the two studies are not the same. It is possible that some ILLUMINATE natural history study participants would be eligible and able to enroll into the IGNITE study. Please speak with your physician or a study investigator for more information.

If I didn't get into the ILLUMINATE natural history study can I possibly be enrolled into the IGNITE study?

Interested individuals should review the inclusion/exclusion criteria with their physician to assess whether they may be a candidate for the IGNITE study.